

## **REMARKS**

In the 25 August 2006 *Office Action*, the Examiner rejects all pending claims, Claims 2-19 and 24-27. Applicant thanks the Examiner with appreciation for the careful consideration and examination given to the Application.

Applicant reserves the right to present new or additional claims in this Application that have similar or broader scope as originally filed. Applicant also reserves the right to present additional claims in a later-filed continuation application that have similar or broader scope as originally filed.

After entry of this Response, Claims 2-19 and 24-27 are pending in the Application. Applicant respectfully asserts that these claims are in condition for allowance and respectfully requests reconsideration of the claims in light of the following remarks. Applicant believes that all pending claims are allowable for the following reasons.

### **I. Pending Claims & Current Rejection**

As the Examiner will recall, embodiments of Applicant's invention are directed toward clinical operational and gain sharing systems. Indeed, the focus of Applicant's currently pending claims is on specific clinical procedures as apposed to non-specific procedures or macro-scale considerations. According to some embodiments, the present invention is a clinical operational information management system that measures clinical utilization and costs. As illustrated in Fig. 3, a process embodiment begins by allocating resources for a specific clinical procedure. The specific clinical procedure is conducted during which time the practitioner utilizes a portion of the allocated resources.

During the specific clinical procedure data is collected related to the allocation of the resources and the conducted specific clinical resource. This collected data is electronically stored in a database. From the collected data, the process identifies reduction operations (such as reduction in waste and costs) of the resources for the specific clinical procedure. The identification of reduction operations occurs prior to establishing a benchmark, because the established benchmark is based upon the identified reduction operations and the utilization of the resource. After the benchmark has been established, the specific clinical procedure is standardized based upon the benchmark. Subsequently, the standardization can be used for conducting the specific clinical procedure, such that fewer resources are allocated and used. *See*

*Specification, Page 10, Line 24 - Page 12, Line 11.* Reducing the products and resources required for a specific clinical procedure, reduces cost and that reduction in cost can be shared with the hospital and the procedure physicians saving the money by following the standardization. Thus, embodiments of the present invention set benchmarks not in the abstract, but with specificity and related to specific clinical procedures.

In contrast, the cited references fail to address (much less disclose or fairly suggest) specifics in setting benchmarks. Indeed, and as discussed in more detail below, because of this failure the primary references (*McCartney & Dang*) can not properly support a prima facie case of obviousness. Further, these same references are not analogous to Applicant's claimed invention because they are not pertinent to the problems solved by Applicant's claimed invention. Finally, the main reference combination (*McCartney & Dang*) would force the modified reference into a configuration unsatisfactory for its intended purpose. For at these reasons, Applicant respectfully asserts that the currently pending claims are allowable over the references of record.

## **II. 35 U.S.C. § 103 Claim Rejections**

The Examiner variously rejects all claims under 35 U.S.C. § 103(a) as allegedly being unpatentable in view of various references. More specifically, the Examiner rejects:

(1) Claims 3-7, 11-18, and 24 due to a combination of *McCartney* (USPN 5,778,345) and *Dang* (USPN 5,835,897);

(2) Claims 8-10 and 19 due to a combination of *McCartney*, *Dang*, and *Jones* (USPN 6,117,073);

(3) Claim 25 due to a combination of *McCartney*, *Dang*, and *Alba* (Article entitled "How hospitals can use internal benchmark data to create effective managed care arrangements," *Journal of Health Care Finance*, Fall 1994);

(4) Claim 26 due to a combination of *McCartney*, *Dang*, *Alba*, and a *CostControl* article (*CostControl* is entitled, "Cost Control Incented Many Ways Despite OIG Ruling on Gainsharing," April 12, 2000, Physician Compensation Report);

(5) Claim 2 due to a combination of *McCartney*, *Dang*, and *CostControl*; and

(6) Claim 27 due to a combination of *McCartney*, *Dang*, and *Kessler* (USPN 5,324,077).

In response to the Examiner's rejections, Applicants respectfully traverse the § 103(a) rejection because the cited references do not support a *prima facie* case of obviousness. As MPEP § 2143 provides, a *prima facie* case of obviousness requires three findings. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations *as a whole* as required by 35 U.S.C. § 103. *See* MPEP § 2142 & § 2143. Here, there are several reasons why the references of record do not properly support a *prima facie* case of obviousness and fail to teach or suggest all the claim limitations as a whole.<sup>1</sup>

**A. *McCartney* and *Dang* Are Not Analogous To Applicant's Claimed Invention And Are Therefore Not Prior Art**

As a preliminary matter, neither *McCartney* or *Dang* are analogous to Applicant's currently claimed invention. As such, these references can not support a rejection to Applicant's currently pending claims. *See* MPEP § 2141.01(a). Just because the references, like Applicant's claimed invention, are somehow related to the medical field does not automatically mean they are analogous art. Rather, as MPEP § 2141.01(a) provides, the key inquiry is whether *McCartney* or *Dang* "would have commended [themselves] to an inventor's attention in considering his problem." *Id.* In this case, Applicant's currently claimed invention deals with and claims specifics ("specific clinical procedure") and benchmarks associated with "specific clinical procedures."

*McCartney* or *Dang* do not focus on or address such specifics, and as such, are not relevant to the particular problems with which Applicant's currently claimed invention addresses. Indeed, *McCartney* describes his invention as "health data process systems . . . on a *macroeconomic* or *macroscopic* scale." (*McCartney*, Col. 1, Lines 4-9) (emphasis added). Likewise, *Dang* is no closer to Applicant's claimed invention in that is directed to profiling and processing medical claims—a topic wholly unrelated to Applicant's invention. (*Dang*, Abstract,

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<sup>1</sup> Because all of the current rejections are based on the *McCartney-Dang* combination, Applicant addresses these references in detail and respectfully asserts that due to the currently pending independent claims being allowable over this main combination, Applicant's pending dependent claims are likewise allowable over the various other reference combinations.

Col. 1, Lines 5-7). In short, due to *McCartney's* and *Dang's* stated fields of endeavor (macroeconomic health systems and medical claim processing) they are not in the Applicant's field of endeavor and are not reasonably pertinent to the particular problems with which Applicant's invention is concerned with and solves. Thus, *McCartney* and *Dang* are not prior art to Applicant's invention. Accordingly, for at least this reason, the rejection due to the *McCartney-Dang* combination is improper, and therefore, Applicant's pending claims are allowable over the *McCartney-Dang* combination.

**B. The *McCartney-Dang* Combination Fails To Teach All of Applicant's Claimed Elements, Limitations, and Features**

Applicant's currently claimed invention is directed toward providing and formulating benchmarks for specific clinical procedures (see Claims for exact language). The Examiner asserts that *McCartney* teaches certain features of Applicant's claimed invention even though *McCartney* fails to teach or fairly suggest such features. Indeed, Applicant respectfully asserts that the Examiner's mischaracterization of *McCartney* is misplaced for several reasons.

For example, *McCartney* does not teach to collect "data related to a specific clinical procedure." That is, the portion of *McCartney* cited by the Examiner does not teach or fairly suggest such a feature. Instead, the portion of *McCartney* cited by the Examiner states that certain information about patients is entered into a "Patient Record Composite Data File." This data collection is not the same as Applicant's claimed "collecting data related to a specific clinical procedure" because it is patient data—not specific clinical procedure data.

Also, *McCartney* fails to teach or fairly suggest identifying from the collected data reduction opportunities for reducing waste and costs during the specific clinical procedure as Applicant claims. Indeed, the portion of *McCartney* cited by the Examiner fails to teach or fairly suggest Applicant's claimed feature. In particular, the cited portion only generally discusses repeating a "benchmark process . . . for other resources including beds, operating rooms, [and] day surgery facilities." (*McCartney*, Col. 18, Lines 30-37). This general discussion, however, makes no mention of reducing costs and wastes during a specific clinical procedure. Rather, this general discussion further illustrates *McCartney's* "macroscopic" scale and its "macroeconomic" endeavor. And it is respectfully submitted that the Examiner's conclusory statements about

*McCartney* can not change that *McCartney* fails to consider, and therefore, fails to teach or fairly suggest Applicant's claimed invention directed toward "specific clinical procedures."

Still yet, *McCartney* does not teach or fairly suggest establishing a benchmark related to a specific clinical procedure. Indeed, while *McCartney* may discuss a "benchmark process" this process does not create, formulate, or establish a benchmark related to a specific clinical procedure as claimed by Applicant. Applicant respectfully asserts that *McCartney* is silent with regard to this claimed feature because *McCartney* is not concerned with such specifics with its "macroscopic" and "macroeconomic" endeavor.

The Examiner also conclusory asserts that *Dang* teaches to standardize the specific clinical procedure based upon a benchmark. However, the portions of *Dang* cited by the Examiner do not have anything to do with specific clinical procedures, much less standardizing specific clinical procedures. Indeed, the cited portion of *Dang* has nothing to do with standardizing any clinical procedures. While *Dang* may speak generally about engineering quality improvement protocols, this does not equate to creating a standard; rather, it fails to state that any standard is ever formulated. Accordingly, *Dang* does not teach to standardize a specific clinical procedure based upon a benchmark.

Because the *McCartney-Dang* combination does not teach Applicant's subject matter as a whole including all of Applicant's claimed elements and limitations, Applicant's claimed invention is allowable over the *McCartney-Dang* combination. Also, because the cited combination does not teach or suggest all the claim limitations as a whole, the cited combination does not support a *prima facie* case of obviousness. Accordingly, for at least these reasons, Applicant respectfully requests withdrawal of the § 103(a) rejections.

**C. The Modified McCartney Reference Would Not Function As Intended And Therefore Cannot Be Modified As Done So By The Examiner**

As mentioned above, Applicant's currently pending claims are rejected due to the main combination of *McCartney & Dang*. In combining these references, the Examiner modifies *McCartney* by adding to it several features from *Dang*. In doing so, Applicant respectfully submits that the Examiner's modification would render *McCartney* unsuitable for its intended purpose. Such modification is not proper and can not support a proper § 103(a) rejection.

Indeed, as MPEP § 2143.01, Section V provides, references can not be modified in such a way that renders them to function unsatisfactory for its intended purpose.

Modifying *McCartney* as done in the *Office Action* is not proper for at least several reasons. First, *McCartney* is not directed to specifics, but rather to macro-level systems and forcing *McCartney* to be directed toward specifics goes against *McCartney's* intended macro-level focus. Second, *McCartney* would not work with *Dang's* "quality improvement protocols" for specific clinical procedures because *McCartney* would then not be optimizing health care procedures on a large, macro-level scale, which is *McCartney's* intended purpose. Finally, the Examiner provides no reasonable expectation of success (or analysis of) how the *McCartney-Dang* combination would provide Applicant's currently claimed invention. Accordingly, *McCartney* can not be modified with *Dang* as the Examiner has done. Withdrawal of the § 103 (a) rejection is, therefore, respectfully requested.

**D. The *McCartney-Dang* Combination Is Improper and Does Not Support A *Prima Facie* Case For Other Reasons**

Applicants respectfully submit that other reasons also exist that weigh against a *prima facie* case of obviousness. These include that the Examiner provides no reasonable expectation of success that Applicants' claimed invention would result from the cited combination as required by MPEP § 2143. Indeed, the Examiner does not at all discuss how combining the cited references (*McCartney & Dang*) would successfully produce Applicants' claimed invention. This is required per MPEP § 2142 & § 2143 for a *prima facie* case of obviousness, and since this requirement has not been met, a *prima facie* case of obviousness has not been set forth.

Also, Applicant respectfully asserts that the cited motivation for combining *McCartney & Dang* does not satisfy MPEP § 2142 & § 2143. That is, the cited motivation has nothing to do with Applicant's focus on specific clinical procedures as apposed to non-specific procedures or macro-scale considerations. Rather, the cited motivation of measuring and quantifying healthcare has nothing to do with formulating and standardizing benchmarks related to specific clinical procedures. Moreover, it is respectfully submitted that one of ordinary skill in the art to which Applicant's invention is concerned would not have combined the *McCartney* and *Dang* as the Examiner has in this instance due to the unrelatedness of Applicant's claimed invention and the cited references. It is also respectfully submitted that due to the focus of *McCartney* and

*Dang* (macroeconomic health systems and medical claim processing) would not lead one of ordinary skill in the art to which Applicant's invention is concerned to combine the references as the Examiner has in this instance. Thus, Applicant respectfully submits that the asserted motivation is not sufficient as required by MPEP § 2143, and as such does not support a *prima facie* case of obviousness.

For at least these reasons, Applicant respectfully submits that all pending claims are allowable over the references of record. Withdrawal of the § 103(a) rejections to all pending claims is respectfully requested because a *prima facie* case of obviousness has not been set forth.

### **III. Fees & Express Request For A One-Month Extension**

Applicant files this *Response* within four months of the 25 August 2006 *Office Action* and with a number of claims less than or equal to those claims previously paid for. Accordingly, Applicant petitions for a one-month extension pursuant to 37 C.F.R. § 1.136 and the undersigned submits the appropriate petition fee via the EFS-Web electronic filing system. No other fees, including claims fees, are believed due. The Commissioner is authorized, however, to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 20-1507.

#### **IV. Conclusion**

This *Response* is believed to be a complete response to the *Office Action* mailed 25 August 2006. Applicant respectfully asserts that the currently pending claims are in condition for allowance and respectfully requests passing of this case in due course of patent office business. If the Examiner believes there are other issues that can be resolved by a telephone interview, or there are any informalities remaining in the application which may be corrected by an Examiner's amendment, a telephone call to Hunter Yancey at (404) 885-3696 is respectfully requested.

Respectfully submitted,  
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